ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

January 13, 2020

Dr. Craig Landau
President and CEO
Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431

Dear Dr. Landau:

We are continuing our work investigating the causes and effects of the opioid epidemic. Last Congress, the Committee on Energy and Commerce began bipartisan investigations into fentanyl, opioid manufacturing, opioid distribution, and the substance use disorder treatment industry. We write today to reactivate the investigation started on August 2, 2018, that examined potential breakdowns in the controlled substances supply chain, which may have contributed to the nation's opioid epidemic, and the role of certain opioid manufacturers in such potential breakdowns.

Last year, we sent a letter to Purdue Pharma requesting information and documents (see attached). Purdue Pharma produced information and documents that were substantially responsive to the August 2, 2018 requests; however, it does not appear that the Committee received responses to request items 16-19. If Purdue Pharma provided documents that were responsive to these request items, please identify the Bates numbers of these documents for each of these requests. If the request items have not yet been addressed, we would request completion of these responses by February 13, 2020.

Since the August 2, 2018, letter, we have become aware of additional issues of concern. To assist our oversight of these matters, we would request that Purdue Pharma respond to the following by February 13, 2020:

1. On February 24, 2019, the CBS program *60 Minutes* explored the Food and Drug Administration's (FDA) decision on changes in Oxycontin's label in 2001 that effectively allowed long-term use of Oxycontin despite the lack of research showing

it was safe or effective for long-term use. Purdue Pharma's public statement to *60 Minutes* denied that the FDA had broadened Oxycontin's use to chronic pain, but in fact had narrowed the indication to "the management of moderate to severe pain when a continuous, around the clock analgesic is needed for an extended period of time." Does Purdue Pharma have any studies showing Oxycontin is safe or effective for continuous, around the clock use for more than 12 weeks? If so, please produce the studies.

2. According to *60 Minutes*, "Purdue told us Oxycontin always was approved for long-term use. But an internal document shows the company was jubilant about the labeling change. Quote: 'The action by the FDA…has created enormous opportunities' to expand the market. The drug company's ads soon extolled the virtues of Oxycontin's effectiveness and sales tripled." How does Purdue Pharma explain the internal document if Purdue in fact perceived FDA's decision only to narrow the indication without any expansion of the label? How does Purdue Pharma explain the apparent changes in the advertising after the label change, and the tripling of sales?

If you have any questions, please contact Jen Barblan or Alan Slobodin of the Minority Staff at (202) 225-3641. Thank you for your prompt attention to this matter.

Sincerely,

Greg Walden
Republican Leader

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

H. Morgan Griffith
Member of Congress

Attachment